



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPPT-2018-0604; FRL-10015-96]**

### **C.I. Pigment Violet 29; Revised Draft Toxic Substances Control Act (TSCA) Risk Evaluation; Notice of Availability, Letter Peer Review and Public Comment**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA is announcing the availability of and soliciting public comment on a revised draft risk evaluation of C. I. Pigment Violet 29 under the Toxic Substances Control Act (TSCA). EPA conducts risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment without consideration of costs or other nonrisk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations, under the conditions of use. The draft risk evaluation has been revised to include information EPA received from the manufacturing stakeholders as a result of a TSCA section 4 order requiring testing of the chemical substance. EPA is announcing the opening of a docket for a 30-day comment period to allow the public to review the revised draft in-light of the additional information. Concurrently with the public comment, EPA is announcing the availability of the risk evaluation for expert letter peer review.

**DATES:** Comments must be received on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-EPA-HQ-OPPT-2018-0604, using the Federal eRulemaking Portal at

<http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not

submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Seema Schappelle, Risk Assessment Division, Office of Pollution Prevention and Toxics (7403M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-8006; email address: [schappelle.seema@epa.gov](mailto:schappelle.seema@epa.gov).

*For peer review information contact:* Dr. Todd Peterson, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-6428; email address: [peterson.todd@epa.gov](mailto:peterson.todd@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. What action is the Agency taking?*

Subsequent to the publication of the C.I. Pigment Violet 29 Draft Risk Evaluation, EPA obtained additional information, including but not limited to information submitted in response to a TSCA section 4 testing order. This additional information triggered revised analyses and the

selection of a different analogue for adverse health effects outcome and dose response. This new information has been placed in the public docket. EPA seeks public comment on the Agency's interpretation and use of the information and its revised calculations. Therefore, EPA is providing 30 days public notice and an opportunity for comment on this revised draft risk evaluation prior to publishing a final risk evaluation (see Unit III.). EPA is also initiating a letter peer review of this revised draft risk evaluation concurrently with the public comment period (see Unit IV.).

*B. Does this action apply to me?*

This action is directed to the public in general. This action may, however, be of interest to those involved in the manufacture, processing, distribution, use, disposal, and/or the assessment of risks involving chemical substances and mixtures. You may be potentially affected by this action if you manufacture (defined under TSCA to include import), process, distribute in commerce, use or dispose of C.I. Pigment Violet 29. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

*C. What is the Agency's authority for taking this action?*

TSCA section 6(b) requires that EPA conduct risk evaluations on existing chemical substances and identifies the minimum components EPA must include in all chemical substance risk evaluations. 15 U.S.C. 2605(b). The risk evaluation must not consider costs or other nonrisk factors. 15 U.S.C. 2605(b)(4)(F)(iii). The specific risk evaluation process is set out in 40 CFR part 702 and summarized on EPA's website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca>.

*D. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit CBI information to EPA through *regulations.gov* or email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact Seema Schappelle listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

## **II. Background**

### *A. What is EPA's risk evaluation process for existing chemicals under TSCA?*

The risk evaluation process is the second step in EPA's existing chemical process under TSCA, following prioritization and before risk management. As this chemical is one of the first ten chemical substances undergoing risk evaluation, the chemical substance was not required to go through prioritization (81 FR 91927, December 19, 2016) (FRL-9956-47). The purpose of conducting risk evaluations is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. As part of this process, EPA must evaluate both hazard and exposure, not consider costs or other nonrisk factors, use reasonably available information and approaches in a manner that is consistent with the requirements in TSCA for the use of the best available science, and ensure decisions are based on the weight of the scientific evidence.

The specific risk evaluation process that EPA has established by rule to implement the statutory process is set out in 40 CFR part 702 and summarized on EPA's website at <http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca>. As explained in the preamble to EPA's final rule on procedures for risk

evaluation (82 FR 33726, July 20, 2017) (FRL-9964-38), the specific regulatory process set out in 40 CFR part 702, subpart B will be followed for the first ten chemical substances undergoing risk evaluation to the maximum extent practicable.

In November 2018, EPA published a draft risk evaluation, which was subject to peer review and public comment. EPA reviewed the peer review report from the Science Advisory Committee on Chemicals (SACC) and public comments, and has revised the risk evaluation in response to these comments as appropriate. The public comments, peer review report, and EPA's draft response are in Docket EPA-HQ-OPPT-2018-0604 at [www.regulations.gov](http://www.regulations.gov). Prior to the publication of the draft risk evaluation, EPA made available the scope and problem formulation, and solicited public input on uses and exposure. EPA's documents and the public comments are in Docket EPA-HQ-OPPT-2016-0725. Additionally, information about the scope, problem formulation, and draft risk evaluation phases of the TSCA risk evaluation for this chemical is available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-pigment-violet-29-anthra219-def6510>

*B. What is C.I. Pigment Violet 29?*

C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f] diisoquinoline-1,3,8,10(2H,9H)-tetrone) is a perylene derivative used to color materials and as an intermediate for other perylene pigments. C.I. Pigment Violet 29 is currently manufactured (including imported), processed, distributed, used, and disposed of as part of industrial, commercial, and consumer conditions of use. Leading applications for C.I. Pigment Violet 29 include use as an intermediate to create or adjust color of other perylene pigments, incorporation into paints and coatings used primarily in the automobile industry, incorporation into plastic and rubber products used primarily in automobiles and industrial carpeting, use in merchant ink for commercial printing, and use in

consumer watercolors and artistic color.

*C. What additional information has been gathered?*

In the draft risk evaluation for C.I. Pigment Violet 29, published in November 2018, EPA preliminarily concluded C.I. Pigment Violet 29 does not present an unreasonable risk of injury to human health or the environment. During the peer review of the draft risk evaluation, members of the SACC highlighted uncertainties in the draft evaluation, specifically concerning C.I. Pigment Violet 29's solubility and occupational worker inhalation exposure.

In response to the SACC comments, in February 2020, EPA issued a TSCA section 4(a)(2) order to two companies, a manufacturer and an importer of C.I. Pigment Violet 29, requiring the development of information necessary to decrease uncertainty in the risk evaluation. The tests ordered by EPA were tailored to address critical uncertainties highlighted by SACC and public comments and were capable of being conducted in a relatively short time period. Section 4 of TSCA authorizes EPA to issue rules, orders, or consent agreements to require the development of new information that is necessary to, among other things, perform a risk evaluation under TSCA section 6(b) or prioritize a chemical substance under TSCA section 6(b) (subject to certain limitations). The EPA test orders required laboratory tests confirming the solubility of C.I. Pigment Violet 29. The other test order required worker respirable dust monitoring of C.I. Pigment Violet 29 in the manufacturing facility. This information has been received and incorporated into the revised draft risk evaluation.

The test order information combined with additional particle size information received from the manufacturers had a significant impact on EPA's analysis of the potential exposure and health effects of PV29. As a result of this updated analysis, the revised draft risk evaluation now shows unreasonable risk for 8 out of 14 conditions of use. Because this important new data had a

significant impact on EPA's risk evaluation and ultimately the risk determinations, the Agency feels it is important that the public have the opportunity to provide input on this new information and analysis before the risk evaluation is finalized.

### **III. Request for Comment**

The docket associated with this request contains the Revised Draft Risk Evaluation, a document that responds to comment received from both the public and peer reviewers on the Draft Risk Evaluation, the SACC Peer Review Report, supplemental files to support the Revised Draft Risk Evaluation, and Charge Questions for the letter peer review.

EPA is seeking public comment on, and information relevant to, the revised draft risk evaluation; in particular, commenters are encouraged to provide comment in-light-of the charge questions supplied to the peer reviewers.

### **IV. Letter Peer Review**

The inclusion of the additional test ordered scientific information resulted in significant changes to the evaluation, including assumptions and models, and ultimately resulted in changes to EPA's risk characterization for this chemical substance. EPA feels it is important that independent, scientific experts have the opportunity to provide input on this new information and analysis before the risk evaluation is finalized, and EPA will conduct an independent expert peer review in the form of a letter peer review simultaneous to the period of solicitation for public comment. Peer reviewers will be provided the identical information made available to the public and will be asked to review the revised draft risk evaluation in-light-of the charge questions posted in the same docket. EPA will consider public and peer review comments as it finalizes the risk evaluation.

**Authority:** 15 U.S.C. 2601 *et seq.*

**Andrew Wheeler,**

*Administrator.*

[FR Doc. 2020-24032 Filed: 10/29/2020 8:45 am; Publication Date: 10/30/2020]